Public Laws : Senate Bills / 110th Congress / 1st Session / 2007

CMS Library
C2-07-13
7500 Security Blvd.
Baltimore, Maryland 21244

II

110TH CONGRESS
1ST SESSION

S. 2221

To amend title XVIII of the Social Security Act to provide for the reporting of sales price data for implantable medical devices.

IN THE SENATE OF THE UNITED STATES

OCTOBER 23, 2007

Mr. GRASSLEY (for himself and Mr. SPECTER) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To amend title XVIII of the Social Security Act to provide for the reporting of sales price data for implantable medical devices.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Transparency in Medical Device Pricing Act of 2007".

SEC. 2. REPORTING OF SALES PRICE DATA FOR IMPLANTABLE MEDICAL DEVICES.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following new section:

"SEC. 1898. REPORTING OF SALES PRICE DATA FOR IMPLANTABLE MEDICAL DEVICES.

"(a) COLLECTION OF SALES PRICE DATA.—

"(1) QUARTERLY REPORTS FROM MANUFACTURERS OF COVERED MEDICAL DEVICES.—Not later than the date that is 30 days after the last day of each fiscal year quarter beginning on or after January 1, 2009, in the case of a covered medical device that is used in a procedure identified under subsection (b), each manufacturer of such device shall submit to the Secretary, in such form as the Secretary shall require, the following:

"(A) The name of the manufacturer of the covered medical device.

"(B) The name of the covered medical device.

"(C) The category type of the covered medical device (using a nomenclature specified by the Secretary for categorizing medical devices in order to ensure consistent reporting).

"(D) The hospital inpatient procedure or hospital outpatient procedure identified under subsection (b) with respect to which the medical device was used during the quarter.

"(E) The average and median sales price of the covered medical device.

"(F) Such other information as the Secretary requires, including the unit of measure used to determine the number of medical devices sold by the manufacturer.

"(2) PENALTIES FOR NONCOMPLIANCE.—

"(A) FAILURE TO SUBMIT INFORMATION.—Any manufacturer of a covered medical device that fails to submit information required under paragraph (1) in accordance with regulations promulgated to carry out such paragraph, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each such failure.

"(B) MISREPRESENTATION.—Any manufacturer of a covered medical device that misrepresents the average or median sales price of such device in information submitted under paragraph (1) shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each such misrepresentation and for each day in which such misrepresented average or median sales price is made publicly available under subsection (c).

"(C) IMPOSITION AND COLLECTION.—A penalty under subparagraph (A) or (B) shall be

imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

"(3) DEFINITIONS.—In this section:

"(A) AVERAGE SALES PRICE.—

"(i) IN GENERAL.—Subject to clauses (ii) and (iii), the term 'average sales price' means, of a covered medical device for a fiscal year quarter for a manufacturer for a unit—

"(I) the manufacturer's sales to all purchasers (excluding sales exempted in clause (ii)) in the United States for such covered medical device in the quarter; divided by

"(II) the total number of such units of such covered medical device sold by the manufacturer in such quarter.

"(ii) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subparagraph, certain sales may be ex-

cluded in the case where the Secretary determines such exclusion is appropriate.

"(iii) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subparagraph, such price shall include volume discounts, cash discounts, free goods and services that are contingent on any purchase requirement, chargebacks, and rebates, and any other discounts or price concessions the Secretary determines to be appropriate (using a methodology developed by the Secretary to estimate costs during the quarter that are attributable to discounts and price concessions).

"(B) COVERED MEDICAL DEVICE.—The term 'covered medical device' means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

"(C) MEDIAN SALES PRICE.—

"(i) IN GENERAL.—Subject to clauses (ii) and (iii), the term 'median sales price' means, of a covered medical device for a fiscal year quarter for a manufacturer for

a unit, the median of all sales by the manufacturer to purchasers (excluding sales exempted in clause (ii)) in the United States for such covered medical device in the quarter.

"(ii) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's median sales price under this subparagraph, certain sales may be excluded in the case where the Secretary determines such exclusion is appropriate.

"(iii) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's median sales price under this subparagraph, such price shall include volume discounts, cash discounts, free goods and services that are contingent on any purchase requirement, chargebacks, and rebates, and any other discounts or price concessions the Secretary determines to be appropriate (using a methodology developed by the Secretary to estimate costs during the quarter that are attributable to discounts and price concessions).

CMS Library
C2-07-13
7500 Security Blvd.
Baltimore, Maryland 21244

"(b) IDENTIFICATION OF PROCEDURES.—For purposes of subsection (a), the Secretary shall identify—

"(1) all hospital inpatient procedures for which payment is provided under section 1886(d) that involve the implantation of a medical device; and

"(2) all hospital outpatient procedures for which payment is provided under section 1833(t) that involve the implantation of a medical device.

"(c) PUBLIC AVAILABILITY.—Not later than April 30, 2009, the Secretary shall establish procedures to ensure that the information reported under subsection (a) is readily accessible to the public through the Internet website of the Centers for Medicare & Medicaid Services in a manner that is easily searchable, downloadable, and understandable. Such procedures shall ensure that the website is updated each quarter as new information is reported under such subsection.".

○

CMS LIBRARY
3 8095 00010258 8